PTO/SB/21 (08-00)

Please type a plus sign (+) inside this box ->	+	
--	---	--

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL JUL 0 8 2004 FORM (to be used for all correspondence after initial filling) Filling Date Filling Date September 10, 2003 First Named Inventor Group Art Unit 1645 Examiner Name Not Yet Known	Init Zsuzanna Nagy Unit 1645 Iame Not Yet Known	OIPE !	Application Number	10/659,578	
JUL 0 8 2004 W FORM First Named Inventor Zsuzanna Nagy	Jnit 1645 Iame Not Yet Known	TRANSMITTAL	Filing Date	September 10, 2003	
I Group Art Unit I 1645	lame Not Yet Known	1111 0 8 2004 W FORM	First Named Inventor	Zsuzanna Nagy	
Examiner Name Not Yet Known		3	Group Art Unit	1645	
	ocket Number 43962-010810	CADEMARY CONTESPONDENCE AREA MINUAL MINI	===	Not Yet Known	
Takal Nicondian of Danaga in This Occionistics		Total Number of Pages in This Submission	Attorney Docket Number	43962-010810	
ENCLOSURES (check all that apply)			ssignment Paners	After Allowance Communication	

ENCLOSURES (check all that apply)							
Fee Transmittal F	Form	Assignment Papers (for an Application)	After Allowance Communication to Group				
Fee Attached	(PTO DEPOSIT ACCOUNT)	Substitute Drawing (Figure 1))	Appeal Communication to Board of Appeals and Interferences				
Amendment		Licensing-related Papers	Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)				
After Final		Petition	Proprietary Information				
Affidavits/dec	claration(s)	Petition to Convert to a Provisional Application	Status Letter				
Extension of Time	e Request	Combined Declaration and New Power of Attorney (9 pages)	Other Enclosure(s) (please identify below):				
Express Abandor	nment Request	Terminal Disclaimer Request for Refund	Form 1449; Copies of References C1-C22; and Post- Card				
Information Discl	osure Statement	Diskette; Number of diskettes:					
Certified Copy of Document(s)	Priority	Remarks	14.11.				
Response to Miss Incomplete Applic							
Response to Missing Parts under 37 CFR 1.52 or 1.53							
	SIGNA	TURE OF APPLICANT, ATTORNEY,	OR AGENT				
Firm or Individual name	James F. Ewing –						
Signature	1 de	YE,					
Date	July 8, 2004						
		CEPTIFICATE OF EVERESS MAIL	INA				

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail Mailing Label

No.: EV426280533US in an envelope addressed to: Mail Stop Amendment – Commissioner for Patents, Post Office Box 1450, Alexandria, VA 22313-1450 on July 8, 2004.

Typed or printed name Anne-Marie Keefe

Signature Date July 8, 2004

comments on the amount of time you are required to complete this form should be send to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231.

143488v1

Approved for use through 10/31/2002. OMB 0651-0032 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

1645

43962-010810

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Complete if Known **EE**TRANSMITTAL 10/659,578 **Application Number** for FY 2003 September 10, 2003 JUL 0 8 2004 Filing Date First Named Inventor Zsuzanna Nagy Pater fees are subject to annual revision. **Examiner Name** Not Yet Known Group / Art Unit

Attorney Docket No.

TOTAL PAYMENT

(\$)

180

									FEE CA	ALCULATION (continued)			
		MET	HOD OF P	AYMENT (chec	k one\			3. ADD	ITIONAL	FEFS			
				ioner is hereby		to cha	raa		Large		Small		
1. ⊠				and credit any					Entity		Entity		
Deposit							· 	Fee Code	Fee (\$)	Fee	Fee (\$)	Fee Description	Fee Pald
Account		50-	2678					1051	130	2051	65	Surcharge - late filing fee or oath	
Number		'						1052	50	2052		Surcharge - late provisional filing fee	
												or cover sheet.	
Deposit								1053	130	1053	130	Non-English specification	
Account		Gre	enberg Tr	aurig, LLP				1812	2,520	1812	2,520	For filing a request for reexamination	
Name								1804	920*	1804	920°	Requesting publication of SIR prior to	
			ional Fee									Examiner action	
			16 and 1.1					1805	1,840*	1805	1,840*	Requesting publication of SIR after	
	37 CF		small entit	y status.				4054	440			Examiner action	
	yment							1251 1252	110 410	2251 2252	55 205	Extension for reply within first month	
' ' -	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,,,,,,						1232	410	2252	205	Extension for reply within second month	
☐ Chec	:k		redit card	☐ Money		Other		1253	930	2253	465	Extension for reply within third month	$\vdash \vdash \vdash \vdash$
							der	1254	1,450	2254		Extension for reply within fourth	\vdash
			FEE C	ALCULATION]	.,.50		. 20	month	
4 DACI	C FILL	NO F						1255	1,970	2255	985	Extension for reply within fifth month	
	C FILI		Entity					1401	320	2401	160	Notice of Appeal	
Large Ent	ity S	maii 88	Fee	Ess Dosseintis	_			1402	320	2402	160	Filing a brief in support of an appeal	
Code (\$)		ode	(\$)	Fee Description	111	Fee	Paid	1403	280	2403	140	Request for oral hearing	
1001 750	20	001	375	Utility filing fee				1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1002 330		002	165	Design filing fee	•			1452	110	2452	55	Petition to revive – unavoidable	
1003 520		003	260	Plant filing fee		<u></u>		1453	1,300	2453	650	Petition to revive – unintentional	
1004 750		004	375	Reissue filing fe		<u> </u>		1501	1,300	2501	650	Utility issue fee (or reissue)	
1005 160) 20	05	80	Provisional filling	g tee			1502	470	2502	235	Design issue fee	
			SUBTOTA	1 (4)		(\$) 0		1503	630	2503	315	Plant issue fee	
		•	001017	- (1)		(4) 0		1460	130	1460	130	Petitions to the Commissioner	
2. EXTRA C	LAIM	FEES	S					1807	50	1807	50	Processing fee under 37 CFR 1.17 (q)	
					Fee from below		Fee Paid	1806	180	1806	180	Submission of Information Disclosure Stmt	180.00
Total Claims		□ -2	20 ** =	0 X] = [0	•				Recording each patent assignment	
Independent Claims		╗.	з =	0 x] = [0	8021	40	8021	40	per property (times number of properties)	
Multiple	L		1	x	· · · · · · · · · · · · · · · · · · ·	┆ ┆╸┌		1809	750	2809	375	Filing a submission after final rejection (37 CFR § 1.129(a))	
Dependent				^ (J L		1810	750	2810	375	For each additional invention to be	
Large Entity Fee F		Sma Fee	II Entity Fee									examined (37 CFR § 1.129(b)) Request for Continued Examination	
		Code		Fee Descrip	tion			1801	750	2801	375	(RCE)	
1202 1	8	2202	2 9	Claims in ex	cess of 20			1802	900	1802	900	Request for expedited examinationof a	
	4	2201		Independent				'	550			design application	
1203 2	80	2203	3 140	Multiple dep				Other fee	e (specify	')			
1204 8	4	2204	4 42	** Reissue ir original pate	nt .				,-F - 2)	-	•		
1205 1	8	2205	5 9	** Reissue c over original		cess of	f 20 and	*Reduc	ed by Bas	sic Filinç	Fee Pa	id SUBTOTAL (3) (\$) 180	
			S	UBTOTAL (2)	(\$) 0								
**Or pumbor =	ravia:	dy oo:	d if greater	; For Reissues, s	aa abawa								
i or uninnet b	GVIUUS	וואט אונ	u. II UI EBIBI	. ruirteissues. S	94 ADOVA								

SUBMITTED BY				Co.	mplete (if applicable)	
Name (Print/Type)	James E Ewing	Degistration No. Attorney/Agent)	52,875	Telephone	617-310-6000	
Signature	الم	127		Date	July 8, 2004	

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.



HE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Zsuzanna Nagy

10/659,578 **SERIAL NO.: GROUP NO.: 1645**

FILING DATE: September 10, 2003 **EXAMINER:** Not Yet Assigned

TITLE: Diagnostic Screens for Alzheimer's Disease

Mail Stop Amendment **Commissioner for Patents** P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents C1-C22 are enclosed.

REMARKS

T.	accordance with	4h.		~£27	CED	1	07	this statement	:-	L	£1.	1 10	VIOCIL P	ONIE).
Ш	accordance with	uit	2 provisions	01.57	C.r.K	. 1.	.y/.	inis statement	18	being	me	116	HECK	UNE

_		or duir	with the provisions of 57 of the 1157, and statement is some mod (official).
[(1)	within three (3) months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the first Office action on the merits, or before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. 1.114; or
[\boxtimes	(2)	after the period defined in (1) but before the mailing date of a final action or a notice of allowance under 37 C.F.R. 1.3 11, and
			the requisite Statement is below, OR
	•		the requisite fee under 37 C.F.R. 1.17(p), namely \$180.00, is included herein, or
[(3)	after the mailing date of a final action or notice of allowance but before the payment of
2004 YPOLIT	E1 00	000133	502678 10659578

07/12/2

Information Disclosure Statement

Serial No.: 10/659,578

Page 2 of 2

the issue fee, AND

the requisite Statement is below, **OR**

the requisite petition fee under 37 C.F.R. 1.17(p), namely \$180.00 is included herein.

A copy of each of the above-identified information is enclosed unless otherwise indicated on the attached Form PTO-1449 (modified). It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims, and signs the enclosed form PTO-1449 to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that: (1) a search has been performed, of the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his/her own conclusion regarding the relevance of the cited information. An early and favorable action is hereby requested. The Commissioner is authorized to charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-2678, Reference No. 43962-010810.

Date: July 8, 2004

Tel. No.: (617) 310-6000 Fax No.: (617) 310-6001

143457v1

Respectfully submitted,

James F. Ewing

Attorney for Applicant(s) Registration No.: 52,875 Greenberg Traurig, LLP One International Place

Boston, Massachusetts 02110

OPlease type a plus sign (+) in this box	+	
/ ⁵ \		

PTO/SB (12-97)
Approved for use through 9/30/00. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

odified Form 1449/0 PADEMARY

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Application Number	10/659,578
Filing Date	September 10, 2003
First Named Inventor	Nagy
Group Art Unit	
Examiner Name	Not Yet Assigned
Attorney Docket Number	43962-010810

				U.S. PATENT DOCUMENTS		· · · · · · · · · · · · · · · · · · ·	
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
					i		

			FOREIGN PATENT DOCUMENTS		
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C1	Arendt T, Holzer M and Gärtner U, "Neuronal expression of cycline dependent kinase inhibitors of the INK4 family in Alzheimer's disease," <u>J Neural Transm</u> , 105: 949-960 (1998)
	C2	Arendt T, Rödel L, Gärtner U, and Holzer M, "Expression of the cyclin-dependent kinase inhibitor p16 in Alzheimer's disease," NeuroReport, 7: 3047-3049 (1996)
	С3	Burke WJ, McLaughlin JR, Chung HD, Gillespie KN, Grossberg GT, Luque FA, and Zimmerman J, "Occurrence of Cancer in Alzheimer and Elderly Control Patients: An Epidemiologic Necropsy Study," <u>Alzheimer Disease and Associated Disorders</u> , Vol. 8: No. 1, pp. 22-28 (1994)
	C4	Darzynkiewicz Z, "Mammalian cell-cycle analysis," <u>The Cell Cycle – A Practical Approach</u> , Fantes P and Brooks R (eds), Oxford University Press, Oxford, pp 43-68 (1993)
	C5	Davies KJ, "The Broad Spectrum of Responses to Oxidants in Proliferating Cells: A New Paradigm for Oxidative Stress," IUBMB Life, 48: 41-47 (1999)
	C6	Drabkin HA and Erickson P, "Down Syndrome and Leukemia, An Update," <u>Etiology and Pathogenesis of Down Syndrome</u> , pp. 169-176 (1995)
	C7	Eckert A, Hartmann H, Förstl H, and Müller WE, "Alterations of Intracellular Calcium Regulation During Aging and Alzheimer's Disease in Nonneuronal Cells," <u>Life Sciences</u> , Vol. 55, Nos. 25/26, pp. 2019-2029 (1994)
	C8	Fischman HK, Reisberg B, Albu P, Ferris SH, and Rainer JD, "Sister Chromatid Exchanges and Cell Cycle Kinetics in Alzheimer's Disease," <u>Biological Psychiatry</u> , 19: 319-327 (1984)
	С9	Mecocci P, Polidori MC, Ingegni T, Cherubini A, Chionne F, Cecchetti R, and Senin U, "Oxidative damage to DNA in lymphocytes from AD patients," Neurology, 51: 1014-1017 (1998)
	C10	Melaragno MI, Smith MDA, Kormann-Bortolotto MH, and Neto JT, "Lymphocyte Proliferation and Sister Chromatid Exchange in Alzheimer's Disease, "Gerontology, 37: 293-298 (1991)

Date of Deposit: July 8, 2004

		C11	Mosmann T., "Rapid Colorimetric Assay for Cellular Growth and Cytotoxicity Assays," <u>Journal of Immunological Methods</u> , 65: 55-6			
Ē		C12	Nagy ZS, Esiri MM, and Smith AD, "The Cell Division Cycle and Neuroscience, 87: 731-739 (1998)	and the Pathophysiology of Alzheimer's Disease,"		
	C106	C13	Payão SL, Smith MdA and Bertolucci PH, "Differential Chromoso Disease, Gerontology, 44: 267-271 (1998)	h MdA and Bertolucci PH, "Differential Chromosome Sensitivity to 5-Azacytidine in Alzheimer's tology, 44: 267-271 (1998)		
8 20	A SULLAND	C14	Schafer AJ and Hawkins JR, "DNA variation and the future of human genetics," Nature Biotechnology, Vol. 16, pp. 33-39 (1998)			
DEM	REL	C15	Sherr CJ, "Growth Factor-Regulated G ₁ Cyclins," Polyfunctionality of Hemopoietic Regulators: The Metcalf Forum. STEM CELLS, 12 (suppl 1): 47-57 (1994)			
		C16	Tatebayashi Y, Takeda M, Kashiwagi Y, Okochi M, Kurumadani T, Sekiyama A, Kanayama G, Hariguchi S, and Nishimura T, "Cell-Cycle-Dependent Abnormal Calcium Response in Fibroblasts from Patients with Familial Alzheimer's Disease, <u>Dementia</u> , 6: 9-16 (1995)			
		C17		ssmann H, and Grubeck Loebenstein B, "APP Peptides Stimulate Lymphocyte Patients With Alzheimer's Disease," Neurobiology of Aging, 17: 541-547 (1996)		
		C18	Wagner EF, Hleb M, Hanna N, and Sharma S, "A Pivotal Role of Cyclin D3 and Cyclin-Dependent Kinase Inhibitor p27 in the Regulation of IL-2-, IL-4-, or IL-10-Mediated Human B Cell Proliferation," <u>Journal of Immunology</u> , 161: 1123-1131 (1998)			
		C19	Araga S, Kagimoto H, Funamoto K and Takahashi K "Lymphocyte Proliferation and Subpopulations in Dementia of the Alzheimer Type" (1990) Jpn J Med 29: 572-5			
		C20	Fong CT and Brodeur GM "Down's Syndrome and Leukemia: Epidemiology, Genetics, Cytogenetics and Mechanisms of Leukemogenesis" (1987) Cancer Genet Cytogenet 28: 55-76			
		C21	McKhann, G. et al., "Clinical diagnosis of Alzheimer's disease: Report of the NINCDS-ADRDA Work Group* under the auspices of Department of Health and Human Services Task Force on Alzheimer's Disease" (1984) Neurology 34: 939-944			
		C22	Nagy Z, Esiri MM, Hindley NJ, Joachim C, Morris JH, King EM-F, McDonald B, Litchfield S, Barnetson L, Jobst KA and Smith AD "Accuracy of Clinical Operational Diagnostic Criteria for Alzheimer's Disease in Relation to Different Pathological Diagnostic Protocols" (1998) <u>Dementia</u> 9: 219-226			
* a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior Serial No, filed, and relied upon for an earlier filing date un 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).						
	Examine Signatur			Date Considered		

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

#143403v1